Sleep One Auto CPAP System
User Manual

CE 1984

EN ISO 9001:2008
EN ISO 13485:2003

Issue date: 02.01.2010 rev00

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SYMBOL DEFINITIONS

	Class II electrical protection–double		Type BF equipment–applied part insulated
	Standby – turns the device on or off		Next Item and adjust the settings on LCD display
	Settings		Previous Item and adjust the settings on LCD display
	Ramp – Starts the ramp function		Heat
	IPX1 Drip-Proof		100 – 240 Volts AC input 50/60 Hz

IMPORTANT SAFEGUARDS

When using electrical products basic safety precautions should always be followed. Read all instructions that is mentioned to this guide before using this device. Important information is highlighted by the following items.

Danger	Urgent safety information for hazards that will cause serious injury or death.
Warning	Important safety information for hazards that might cause serious injury.
Caution	Information for preventing damage to the product.
Note	Information to which you should pay special attention.

READ THESE INSTRUCTIONS CAREFULLY BEFORE USING THIS DEVICE.

KEEP THESE INSTRUCTIONS

DANGER
Electrical shock hazard, do not use device while bathing.
Electrical shock hazard, do not immerse this device into water or any other liquid.

Electrical shock hazard, do not attempt to open or remove the case. There are no user serviceable internal components.

SleepOne should be used only with masks recommended by Kare Medical.

SleepOne is not a life support device and may stop operating with certain device faults or with a power failure.

To avoid electric shock, always unplug power cord from outlet power source when performing cleaning.

Use only accessories recommended by Kare Medical Ltd Co.

CAUTION–Never rinse or place the device in water. Never allow liquids to get into or around any of the ports, switches or air filter; doing so will result in device damage. If this occurs, discontinue use and remove the power cord from the power source. Allow the device to completely dry before use.

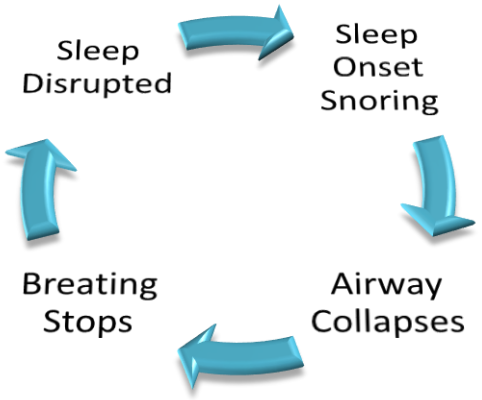
CAUTION–Do not places the SleepOne device where it can be fallen down the floor or where the power cord may create a trip hazard.

CAUTION–Oxygen is a prescription gas and should only be administered under the supervision of a doctor.

GENERAL INFORMATION

SleepOne is a CPAP device which is intended for use in treating Obstructive Sleep Apnea (OSA).

Obstructive sleep apnea (OSA) is the most common category of sleep-disordered breathing. The muscle tone of the body ordinarily relaxes during sleep, and at the level of the throat the human airway is composed of collapsible walls of soft tissue which can obstruct breathing during sleep. It can be seen process of OSA on the following diagram.



Cycle of Obstractive Sleep Apnea

Individuals with low muscle tone and soft tissue around the airway (e.g., because of obesity) and structural functions that give rise to a narrowed airway are at high risk for obstructive sleep apnea. The elderly are more likely to have OSA than young people. Men are more typical sleep apnea sufferers than women and children, although it is not uncommon in the latter two.

The most common treatment for sleep apnea is the use of a continuous positive airway pressure (CPAP) device, which 'splints' the patient's airway open during sleep by means of a flow of pressurized air into the throat.

CONTRAINDICATION

Positive airway pressure may be contraindicated in some patients with the following conditions:
• Pneumothorax or pneumomediastinum
• Pathologically low blood pressure, particularly if associated with intravascular volume depletion
• Cerebrospinal fl uid leak, recent cranial surgery or trauma
• Severe bullous lung disease
• Dehydration.

SleepOne CPAP Device

SleepOne continuous positive airway pressure (CPAP) device was initially used mainly by patients for the treatment of sleep apnea at home. Obstructive sleep apnea occurs when the upper airway becomes narrow as the muscles relax naturally during sleep. This reduces oxygen in the blood and causes arousal from sleep. SleepOne CPAP device stops this phenomenon by delivering a stream of compressed air via a hose to a nasal pillow, nose mask or full-face mask, splinting the airway (keeping it open under air pressure) so that unobstructed breathing becomes possible, reducing and/or preventing apneas and hypopneas.

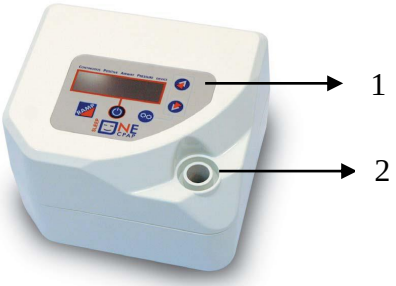
PARTS AND ACCESSORIES

SYSTEM CONTENTS

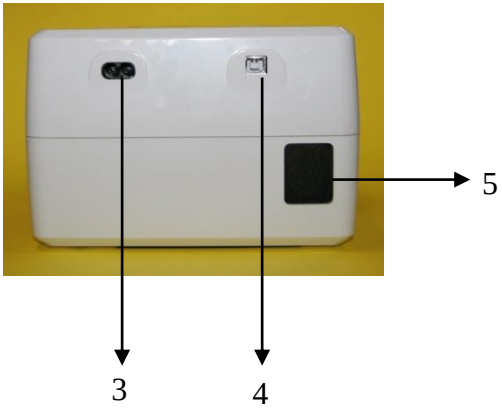
1. Sleep One Device
2. AC Cord
3. Carrying Case
4. Air Supply Tube
5. User Manual

ACCESSORIES

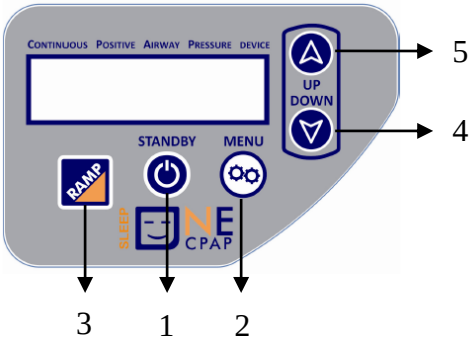
1. Heater-Humidifier
2. CPAP Masks



1. Keypad/LCD Display
2. Air Supply Port on Top



3. AC Connector
4. USB Port
5. Air Inlet Filter



1. Standby – turns the device on or off
2. Settings
3. Ramp – Starts the ramp function
4. Previous Item and Adjust the Settings on LCD Display
5. Next Item and Adjust the Settings on LCD Display

ASSEMBLY OF SLEEPONE DEVICE

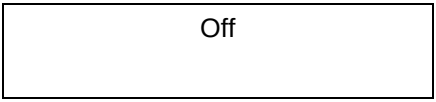
1. Place the SleepOne on a stable surface. Ensure that the air inlet in the back of the device is not blocked by anything.

NOTE– *Never place the SleepOne device on a soft surface.*

2. Insert the power cord into the back of the device. Make sure the power cord is fully inserted into the connector. Plug the other end of the power cord into the AC outlet.
3. Attach the air supply tubing to the air supply interface on the top of the device.
4. Prepare the mask by referring to the mask's instruction guide.
5. Connect the air supply tubing to the mask.

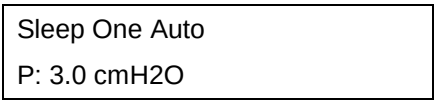
INSTRUCTION FOR USE

To begin operation, verify that your SleepOne is connected to a 'power source. When plugged in, the LCD display should appear as noted.

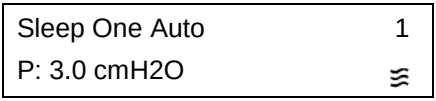


Put on your CPAP mask and press the ON/OFF button on the keypad to turn on airflow or put on your CPAP mask and take a few breaths to turn on airflow automatically. If the device does not automatically start after taking 2-3 breaths, Auto On function may have been disabled. If Auto ON is disabled, you must manually press the ON/OFF button to start and stop the device. The pressure in your mask will rise to the set pressure in a while.

The display shows the actual mask pressure while the device is in use. Because this is the actual pressure, the device pressure reading may vary slightly as you breathe. Your display should appear as noted.



If your SleepOne CPAP system includes a humidifier, its heater controls and status are displayed as noted in the image.



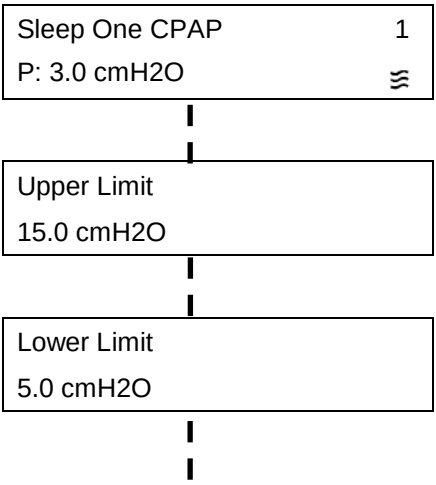
Press the ON/OFF button to turn the device off. You may also simply remove your mask. After a few seconds the device will display the message “Mask Off” If you do not put the mask on again the device will automatically turn off after a while. If the device does not turn off automatically, the Auto Off function may have been disabled. In this case you must manually turn the device off.

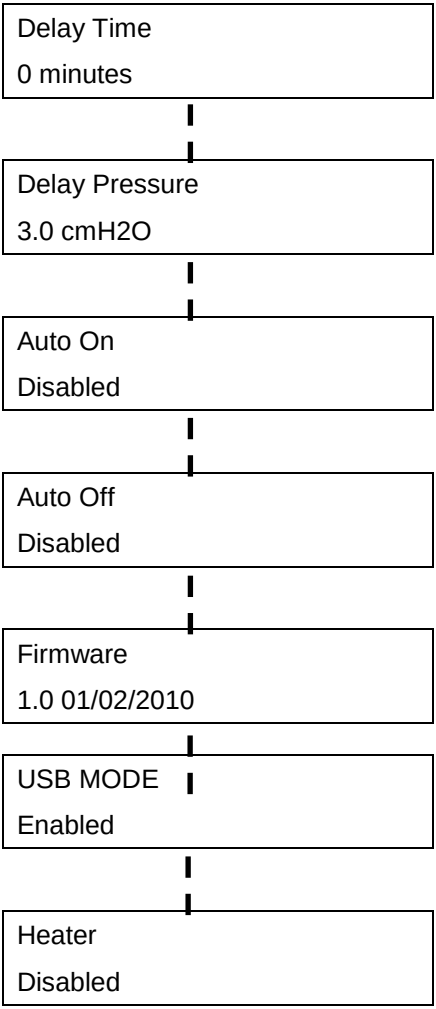
Patient Menu Control

Sleep One Auto 1 P: 3.0 cmH2O ≋	This is the default screen for SleepOne CPAP System. The actual mask pressure and heater setting are shown. To reach menu items, press to Settings button once.
Upper Limit 15.0 cmH2O	This is a setting which limits the maximum pressure at which the Sleep One will operate if in Auto mode.To activate the Upper Limit Menu first press the Ramp button. While holding the Ramp button, press Settings button. Use the Up and Down button to adjust the settings.
Lower Limit 5.0 cmH2O	This is a setting which limits the minimum pressure at which the Sleep One will operate if in Auto mode.To activate the Lower Limit Menu first press the Ramp button. While holding the Ramp button, press Settings button. Use the Up and Down button to adjust the settings.
Delay Time 0 minutes	Selectable delay time setting. To activate the Delay Time Menu press Settings button. Use the Up and Down button to adjust the settings.
Auto On Disabled	This option controls the Auto-ON function, which automatically starts the flow of air after breathing once or twice into the mask. To activate the Auto On Menu press Settings button. Use the Up and Down button to adjust the settings.

Auto Off Disabled	This option controls the Auto-OFF function, which automatically stops the flow of air after taking off the mask. To activate the Auto Off Menu press Settings button. Use the Up and Down button to adjust the settings.
Firmware 1.0 01/02/2010	Shows version of installed firmware.
USB MODE Disabled	To Activate the USB Mode, press Settings button. Use the Up and Down button to adjust the settings.
Heater Disabled	This option controls the Heater functions if the heater. To Activate the Heater Menu, press Settings button. Use the Up and Down button to adjust the settings.

The following chart shows each Display you will scroll through using the Up or Down buttons after pressing the Settings button on the keypad. Once the final Display is reached, pressing the Next button will return you to the first Display.




Delay Time
0 minutes
Delay Pressure
3.0 cmH2O
Auto On
Disabled
Auto Off
Disabled
Firmware
1.0 01/02/2010
USB MODE
Enabled
Heater
Disabled

Clinical Menu Control

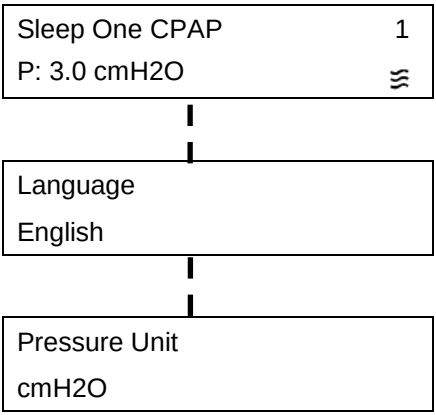
To activate the Clinical Menu first press the Down Button. While holding the Down button, press Standby button. Use the Up and Down button to adjust the settings.

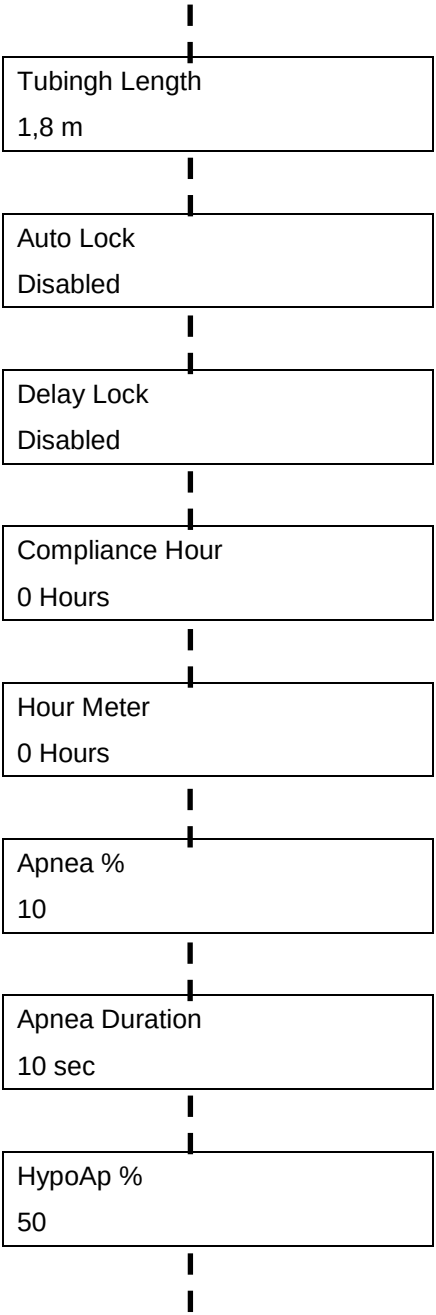
Sleep One CPAP 1 P: 3.0 cmH2O ≋	This is the default screen for SleepOne CPAP System. The actual mask pressure and heater setting are shown. To reach menu items, press to Settings button once.
Language English	This function is used for selecting preferred language. To activate the function, press Settings button and then use the **Up** and **Down** button to select preferred language.
Pressure Unit cmH2O	This function is used for selecting preferred pressure unit. To activate the function, press Settings button and then use the **Up** and **Down** button to select preferred pressured unit. (cmH2O –mbar – hPa)
Tubingh Length 1,8 m	By this function, you can adjust air supply tubing length of Sleep One device. The standard tubing length supplied with the device is 1.8 meters. To activate the function, press Settings button and then use the **Up** and **Down** button to select preferred air supply tubing length. (1,8 m – 3 m)
Auto Lock Disabled	This function is used for locking the Auto Off and Auto On feature. To activate the function, press Settings button and then use the **Up** and **Down** button to adjust the settings.
Delay Lock Disabled	This function is used for lock the Delay feature. To activate the function, press Settings button and then use the **Up** and **Down** button to adjust the settings.

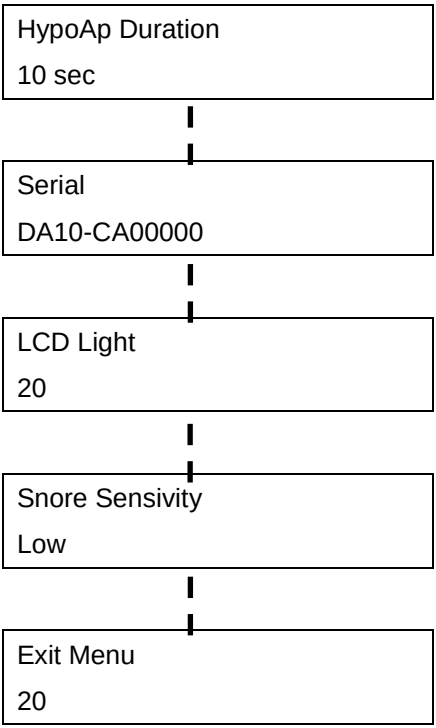
Compliance Hour 0 Hours	The total number of hours that the Sleep One has been providing therapy.
Hour Meter 0 Hours	The total number of hours that the Sleep One has been in operation.
Apnea % 10	The absolute values below which the respirotory flow must fall to be considered as an apnea. To activate the function, press Settings button and then use the **Up** and **Down** button to adjust the settings. (Range 0 – 20, increments of 5)
Apnea Duration 10 sec	The number of seconds the respiratory flow must remain below the apnea percent to be detected as an apnea. To activate the function, press Settings button and then use the **Up** and **Down** button to adjust the settings. (Range 6 – 150 sec, İncrements of 2)
HypoAp % 50	The percent which the respiratory flow must fall from its normal value to be considered as a hypopnea. To activate the function, press Settings button and then use the **Up** and **Down** button to adjust the settings. (Range 30 – 70, increments of 5)
HypoAp Duration 10 sec	The number of seconds the respiratory flow must remain below the hypopnea percent to be detected as an hypopnea. To activate the function, press Settings button and then use the **Up** and **Down** button to adjust the settings. (Range 6 – 150 sec, İncrements of 2)

Serial DA10-CA00000	Shows the serial number of the device.
LCD Light 20	This setting changes the duration of LCD display light. To activate the function, press Settings button and then use the **Up** and **Down** button to adjust the settings. (20 – 40 – 60)
Snore Sensivity Low	To activate the function, press Settings button and then use the **Up** and **Down** button to adjust the settings. (Range Low - High)
Exit Menu	To exit to patient menu press Settings button.

The following chart shows each Display you will scroll through using the Up or Down buttons after pressing the Settings button on the keypad. Once the final Display is reached, pressing the Next button will return you to the first Display or press Settings button to return Patien Menu.




Tubingh Length
1,8 m
Auto Lock
Disabled
Delay Lock
Disabled
Compliance Hour
0 Hours
Hour Meter
0 Hours
Apnea %
10
Apnea Duration
10 sec
HypoAp %
50



MAINTENANCE AND CLEANING

DANGER

Electric shock hazard – Do not attempt to open or remove the case; there are no user-serviceable components inside. If service is required, contact your provider.

WARNING

If the operation of the device appears to get out of normal operation or begins to be heard unusual sounds, do not continue to use device and contact your provider company.

If the device has been fallen down, verify functionality of the device. If the device does not function or the case is damaged, do not continue to use device and contact your provider company.

If the device does not appear to be functioning properly refer to the possible problems and how to solve them section for instructions.

Standard Air-Inlet Filter–Check the filter every 10 days and clean it if necessary. Replace the filter every 6 months or sooner if it is damaged.

CAUTION–Never rinse or place the device in water. Never allow liquids to get into or around any of the ports, switches or air filter. *If this occurs, do not use the device. Contact your provider company for service.*

Device Case Cleaning

1. Unplug the SleepOne from the power source. Use a clean dry cloth and mild detergents for cleaning the unit.
2. Allow the device to dry completely before plugging it into a power source.

Filter Cleaning

Air-Inlet Filter (Standard)

1. The air-inlet filter should be checked every 10 days and cleaned as necessary. The filter is located in the rear of the device.

CAUTION– *Proper filter function is important for the operation of the device and to protect the device from damage.*

2. To clean, remove filter from the frame.
3. Wash the filter in a solution of warm water and mild detergent, and rinse with water. Allow the filter to dry completely. If the filter is damaged, contact your provider company for a replacement.
4. Ensure the filter is completely dry before installation and use.

Tubing

The air supply tubing should be cleaned daily. Remove the tubing from the device and mask. Use a mild detergent and water to clean the inside of the tubing. Rinse the tubing and allow to air dry.

POSSIBLE PROBLEMS AND HOW TO SOLVE THEM

Possible Problem	Reason	Solution
Display shows nothing.	1. Device is not plugged in or the power cord is not firmly fitted to outlet power. 2. There is no outlet power.	1. Ensure that power cord is firmly fitted to the SleepOne and the power outlet. 2. Ensure outlet power is live
SleepOne does not start when breathing into the mask.	1. The Auto-ON function has been disabled. 2. There is no power to the device. 3. Breath is not deep enough for the Auto-ON function to detect. 4. The air supply port plug is missing or not firmly fitted. 5. The humidifier chamber is not fully engaged into the cradle or is missing.	1. Use the ON/OFF button to start and stop the device. 2. Ensure that power cord is firmly fitted to the SleepOne and the power outlet. 3. Breathe deeper to start the SleepOne. 4. Make sure the air supply port plug is firmly fitted into the unit.
The airflow has stopped suddenly during use.	1. The Auto-OFF function has detected large airflow because of wrong placed mask. 2. During use you may breathe by mouth.	1. Ensure you have a good mask fit; adjust the mask and headgear as needed. 2. Contact your provider company for a chin strap or different mask which will help prevent mouth breathing. If problem is not resolved with above solutions, disable Auto-OFF function.
The display shows an error.	1. An error has occurred in the device and requires servicing.	1. Contact your provider company for service.

Symptoms of OSA have recurred.	1. Air filter may be obstructed. 2. Sleep apnea condition has changed.	1. Clean or replace the air filter and change the location of device against drapes and other dusty surfaces. 2. Contact your doctor.
Dryness of throat or nose.	1. Inadequate humidity.	1. Add Heated Humidifier. 2. Increase the heater setting on the humidifier.
Condensation of water is collecting in the hose causing a gurgling noise.	1. Your humidification setting is too high. 2. The room temperature fluctuates from higher to lower levels through the night.	Reduce the humidifier heater setting and/or increase the temperature of the room.
Air from flow generator seems to be too warm.	1. The air filter(s) is/are dirty. 2. The air inlet port is blocked. 3. The room temperature is too high. 4. The SleepOne is located near a heat source.	1. Refer to the filter cleaning section for instructions on filter maintenance. 2. Unblock the air inlet. 3. Decrease the room temperature. 4. Locate the device away from the heat source so the air being drawn into the device is at room temperature. If the problem persists contact your provider company.
Nasal, sinus or ear pain, possibly with runny nose.	1. You may have a reaction to air flow pressure.	1. Do not continue to use and contact your doctor.

SPECIFICATIONS

Size..... 18.1 x 15.5 x 11.7 cm
Weight..... 1.20kg
Electrical Requirements..... 100-230 V AC
Maximum Power Consumption..... 50W
Pressure Range.....3-20 cm H2O
Operating Temperature Range..... 5°C to 40°C
Operating Humidity Range..... 0% to 95% RH
Sound Level (tested per ISO 17510)..... <29dB
Equipment classification (protection from electric shock)……..... Class II
Degree of protection from electric shock.....Type BF Applied Part
Degree of protection against ingress of liquids.....IPX1
Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.
Mode of operation..... Continuous

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